

REGISTRATION OF ORD SPONSORED CLINICAL TRIALS

The VA Office of Research and Development registers its clinical trials to facilitate access by our veteran population and the general public to these important research studies on diseases and/or disorders that affect them.

ORD currently has established processes for registering the trials it sponsors. The studies that have been identified as clinical trials and some observational studies are registered in the National Library of Medicine's clinicaltrials.gov (<http://www.clinicaltrials.gov>) registry. However, to assist investigators conducting VA-sponsored clinical trials with ensuring registration, the following information is being provided.

It should be noted that in addition to recent efforts by the U.S. Congress and World Health Organization to increase clinical trials registration, the International Committee of Medical Journal Editors (ICMJE) has issued a statement that it will consider a clinical trial for publication only if it has been registered in a registry that meet certain criteria (http://www.icmje.org/clin_trialup.htm).

Specifically, the ICMJE will require that trials beginning participant enrollment on/after **July 1, 2005**, be registered prior to enrollment in order for results to be considered for publication. For trials that began enrollment prior to this date, the ICMJE member journals will require registration by **September 13, 2005** before considering the trial for publication.

Further questions concerning individual Service registration procedures can be directed to the following trials registry program managers:

Clinical Science Research & Development Service / Cooperative Studies Program

and

Biomedical Laboratory Research & Development Service

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